

Remarks

Claims 37-40 and 42-46 are pending in this application. The specification has been amended by deleting the prior sequence listing and inserting the new sequence listing. Claim 38 has been amended to correct typographical errors. No new matter is added with these amendments. These amendments are made without prejudice or disclaimer. Applicants reserve the right to prosecute any cancelled or otherwise unclaimed subject matter in this or a separate application, as appropriate. Consideration and entry of these remarks and amendments is respectfully requested.

I. Sequence Listing

A new Sequence Listing is attached in both paper and computer-readable form. The undersigned hereby declares that the content of the paper and computer readable copies of the Sequence Listing submitted herewith are identical in content and include no new matter. The specification has been amended to insert the Sequence Listing.

II. Rejections Under 35 U.S.C. § 112, Second Paragraph

Claim 38 stands rejected under 35 U.S.C. § 112, second paragraph as being indefinite with respect to the meaning of “druggable target”. (Office Action, page 3.) The Examiner questions how a druggable target is differentiated from a target that is not druggable.

The concepts of druggable and non-druggable targets are presented at paragraphs target” at paragraphs 0005-0007 of the instant specification. For instance, paragraph 005 states:

A druggable target is a gene whose function can be modulated by a drug, such as an organic molecule with one or more pharmacological activities. The number of gene targets within the human genome that are of pharmaceutical relevance is limited. Presently, the pharmaceutical industry is focusing primarily on certain areas of high interest, such as CNS (central nervous systems) disorders, metabolic diseases, cardiovascular diseases, oncology, inflammation and infectious diseases. Within these areas, each pharmaceutical company has identified their own prioritized list of “druggable targets”.

The term “druggable target” is generally understood by those of skill in the art to have the meaning described in paragraph 0005. A druggable target is one having activity that can be modulated by a drug having pharmaceutical relevance. In contrast, a non-druggable target is one

that is not affected in any pharmaceutically relevant manner. Applicants believe the term would be clear to one of skill in the art given the general understanding of the term by skilled artisans and the description provided by the instant specification. Accordingly, it is respectfully requested that this rejection be withdrawn.

III. Rejections Under 35 U.S.C. § 102(e)

The Examiner alleged that the invention of claims 37-40, 44 and 46 are anticipated under 35 U.S.C. § 102(e) by Dumas Milne Edwards (U.S. Pat. No. 7,060,479; hereinafter referred to as the '479 patent). (Office Action, page 3.) Applicants respectfully disagree for the reasons discussed below.

The individual members of the instantly claimed clone collections each comprise at least one suppressible stop codon. Examiner alleged that the inclusion of one or more suppressible stop codons within the instantly claimed library members is an "inherent feature" of the stop codons of the '479 patent because "they at least can be artificially mutated into nonstop codons such that they are suppressed." However, to establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the cited reference and that it would have been so recognized by one of ordinary skill in the art. *In re Robertson*, 169 F.3d 743 (Fed. Cir. 1999); *Transclean Corp. v. Bridgewood Serv. Inc.*, 290 F.3d 1346 (Fed. Cir. 2002). The Examiner has not shown that suppressible stop codons were necessarily present in the clone collections of the '479 patent.

As described in paragraph 0285 of the instant application, a suppressible stop codon is one that has been made, for example, more suppressible by any of several methods including (but not limited to) inserting an adenosine immediately following the stop codon. The '479 patent does not disclose any such modifications to stop codons. The Examiner has merely alleged that a clone of the '479 patent could be modified to include a suppressible stop codon. The Examiner has not shown that the reader of the '479 patent would have necessarily concluded that a suppressible stop codon was disclosed thereby. The Examiner's allegation of inherency is in conflict with the case law, and as such is improper.

The Examiner also alleges that the '479 patent discloses a collection of 241 clones which fits "into the range of about 50 to about 100,000 clones". However, the clones of the '479 patent

do not contain suppressible stop codons, as defined by the instant specification, and are therefore not anticipatory. The instantly claimed collection of clones requires each member of the collection to contain a suppressible stop codon; the clones of the '479 patent have not been shown to contain suppressible codons. As such, those clones do not in fact fall within the claimed range.

The Examiner also alleged that claims 38-40 and 44 are anticipated by the '479 patent because it discloses clone collections relating to G protein-coupled and EGF receptors. It was also alleged that the invention of claim 47 was anticipated because the '479 patent also teaches the use of tags. As described above, Applicants believe the '479 patent is deficient as to clones containing suppressible stop codons. These rejections add nothing to the Examiner's allegations that the '479 patent inherently discloses suppressible stop codons. As such, Applicants respectfully maintain that these rejections are improper.

For the reasons set forth above, Applicants respectfully maintain that these 102(e) rejections are improper. As such, it is respectfully requested that these rejections be withdrawn.

IV. Rejections Under 35 U.S.C. § 103(a)

A. Claims 42 and 45

Claims 42 and 45 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the '479 patent in view of Stearman *et al.* (Science, 271: 1552-1557, 1996). (Office Action, page 7.) Applicants respectfully disagree as indicated below.

The Examiner relied upon the reasoning of the 102(e) rejection with respect to the '479 patent. In that rejection, it is alleged that the '479 patent teaches suppressible stop codons because the same "at least can be artificially mutated into nonstop codons such that they are suppressed." As discussed above, Applicants do not agree that the '479 patent inherently discloses suppressible stop codons. It is well-settled that the mere fact that the prior art may be modified does not make the modification obvious unless the prior art suggests the desirability thereof. *In re Lahu*, 747 F.2d 703, 223 USPQ 1257 (Fed. Cir. 1984). The Examiner has not provided evidence of any such desirability. While the '479 patent teaches the use of stop codons in general, it does not teach modification of stop codons or other elements affecting the same to

provide increased suppressibility. As such, Applicants do not believe the '479 patent is a reference upon which a proper obviousness rejection may be based.

As to the combination of references, the Examiner is required to provide "a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references" and has not done so. (*See* Manual of Patent Examining Procedure (MPEP) § 706.02(j) (eighth edition, revision 5, August 2006).) In the rejection, the Examiner merely alleges that it would have been obvious to modify the '479 patent using the tag of Stearman because the claimed invention amounts to nothing more than "a simple substitution of one known element (a suppressible stop codon that is inserted in-frame) to yield a predictable result", citing *KSR*. First, Applicants strongly disagree that the claimed invention results from a "simple substitution"; the '479 patent does not teach suppressible stop codons. Furthermore, while simple substitution may be a rationale for obviousness, *KSR* also clearly stated that there must be "some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness". *KSR Int'l Co. v. Teleflex Inc.*, No. 04-1350 (U.S. 4/30/2007) (2007) (p. 14) citing *In re Kahn*, 441 F.3d 977, 988. The Examiner's allegation lacks any explanation as to why one would have combined the references or any reasoned support for the rejection. Merely concluding the invention is obvious because one could substitute one element for another without any articulated reasoning is improper. As stated at MPEP § 706.02(j), "[i]t is important for an examiner to properly communicate the basis for a rejection so that the issues can be identified early and the applicant can be given fair opportunity to reply." Applicants respectfully maintain that the conclusion of obviousness has been communicated but a reasoned basis for the rejection has not, and that the rejection is therefore improper. Accordingly, it is respectfully requested that this rejection be withdrawn.

B. Claim 43

Claim 43 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over the '479 patent in view of Senecoff et al. (*JBC*, 261: 7380-7386 (1986)). (Office Action, page 9.) Applicants respectfully disagree as indicated below.

With respect to the '479 patent, the Examiner relies upon the reasoning of the 102(e) rejection. In that rejection, it is alleged that the '479 patent teaches suppressible stop codons

because the same “at least can be artificially mutated into nonstop codons such that they are suppressed.” As discussed above, Applicants do not agree that the ‘479 patent inherently discloses suppressible stop codons. It is well-settled that the mere fact that the prior art may be modified does not make the modification obvious unless the prior art suggests the desirability thereof. *In re Lahu*, 747 F.2d 703, 223 USPQ 1257 (Fed. Cir. 1984). The Examiner has not provided evidence of any such desirability. While the ‘479 patent teaches the use of stop codons, it does not teach modification of stop codons or other elements affecting the same to provide increased suppressibility. As such, Applicants do not believe the ‘479 patent is a reference upon which a proper obviousness rejection may be based.

As to the combination of references, the Examiner is required to provide “a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references” and has not done so. MPEP 706.02(j). In the rejection, the Examiner merely alleges that it would have been obvious to modify the ‘479 patent using the Senecoff because the reference “has the ability of using recombination sites for the purposes of understanding directionalities of specific proteins”. First, Applicants strongly disagree that the claimed invention results from a “simple substitution”; the ‘479 patent does not teach suppressible stop codons. Furthermore, in *KSR*, the Court clearly stated that there must be “some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”. *KSR Int’l Co. v. Teleflex Inc.*, No. 04-1350 (U.S. 4/30/2007) (2007) (p. 14) citing *In re Kahn*, 441 F.3d 977, 988. All the Examiner has done is stated that Senecoff teaches recombination sites and concluded that it would have been obvious to combine this with the ‘479 patent to produce the instantly claimed invention. Merely concluding the invention is obvious without any articulated reasoning is improper. As stated at MPEP 706.02(j), “[i]t is important for an examiner to properly communicate the basis for a rejection so that the issues can be identified early and the applicant can be given fair opportunity to reply.” Applicants respectfully maintain that the conclusion of obviousness has been communicated but a reasoned basis for the rejection has not, and that the rejection is therefore improper. Accordingly, it is respectfully requested that this rejection be withdrawn.

Conclusion

Applicants believe that a full and complete Reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned.

Prompt and favorable consideration of this Reply is respectfully requested.

Respectfully submitted,

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